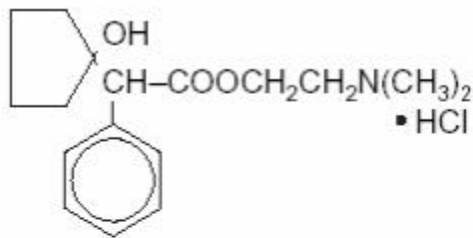


## CYCLOMYDRIL - cyclopentolate hydrochloride and phenylephrine hydrochloride solution/ drops

Alcon

### DESCRIPTION

CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) is a mydriatic prepared as a sterile topical ophthalmic solution. The active ingredients are represented by the chemical structures:

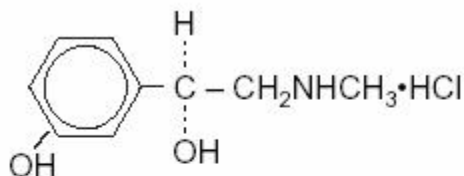


Established name:

Cyclopentolate Hydrochloride

Chemical name:

2-(Dimethylamino)ethyl 1-hydroxy-  
α-phenylcyclopentaneacetate  
hydrochloride



Established name:

Phenylephrine Hydrochloride

Chemical name:

3-hydroxy - α[(methylamino)  
-methyl]-, Benzenemethanol,  
hydrochloride (*R*)-.

**Each mL contains:** **Active:** cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** edetate disodium, boric acid, hydrochloric acid and /or sodium carbonate (to adjust pH), purified water.

### CLINICAL PHARMACOLOGY

Cyclopentolate hydrochloride is an anticholinergic drug and Phenylephrine hydrochloride is an adrenergic drug. This combination induces mydriasis that is greater than that of either drug alone at its respective concentration. The concentrations of cyclopentolate hydrochloride and phenylephrine hydrochloride have been selected to induce mydriasis with little accompanying cycloplegia. Heavily pigmented irides may require more doses than lightly pigmented irides.

### INDICATIONS AND USAGE

For the production of mydriasis.

### CONTRAINDICATIONS

Do not use in patients with untreated narrow-angle glaucoma or with untreated anatomically narrow angles or where there is hypersensitivity to any component of this preparation.

### WARNINGS

FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION. The use of this combination may have an adverse effect on individuals suffering from cardiovascular disease, hypertension, and hyperthyroidism, and it may cause CNS disturbances. Infants are especially prone to CNS and cardiopulmonary side effects from cyclopentolate. Observe infants closely for at least 30 minutes. Mydriatics may produce a transient elevation of intraocular pressure.

## **PRECAUTIONS**

### **General**

The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to reduce excessive systemic absorption. Caution should be observed when considering use of this medication in the presence of Down's syndrome and in those predisposed to angle-closure glaucoma. The effect of long-term use of this preparation has not been established, therefore, it should be restricted to short-term use.

### **Information for Patients**

Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in hazardous activities while pupils are dilated. Patient may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination.

### **Drug Interactions**

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

There have been no long-term studies done using cyclopentolate hydrochloride and/or phenylephrine hydrochloride in animals to evaluate carcinogenic potential.

### **Pregnancy**

Pregnancy Category C. Animal reproduction studies have not been conducted with cyclopentolate hydrochloride and/or phenylephrine hydrochloride. It is also not known whether cyclopentolate hydrochloride and/or phenylephrine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CYCLOMYDRIL® Ophthalmic Solution should be given to a pregnant woman only if clearly needed.

### **Nursing Mothers**

It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CYCLOMYDRIL Ophthalmic Solution is administered to a nursing woman.

### **Pediatric Use**

Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances in pediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children, and in children with spastic paralysis or brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination. Observe infants closely for at least 30 minutes (See **WARNINGS**).

### **Geriatric Use**

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

## **ADVERSE REACTIONS**

### **Ocular**

The following ocular adverse experiences have been associated with the use of CYCLOMYDRIL: increased intraocular pressure, burning/irritation upon instillation, photophobia, blurred vision and superficial punctate keratitis.

### **Non-ocular**

Use of cyclopentolate hydrochloride has been associated with psychotic reactions and behavioral disturbances in children. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. This drug produces reactions similar to those of other adrenergic and anticholinergic drugs; however, the central nervous system manifestations as noted above are most common. Other manifestations of adrenergic and anticholinergic topical ophthalmic drugs include tachycardia, hyperpyrexia, hypertension, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis and death.

## **OVERDOSAGE**

Excessive dosage may produce behavioral disturbances, tachycardia, hyperpyrexia, hypertension, elevated intraocular pressure, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Patients exhibiting signs of overdosage should receive supportive care and monitoring.

**DOSAGE AND ADMINISTRATION**

Instill one drop in each eye every five to ten minutes. To minimize systemic absorption, apply pressure over the nasolacrimal sac for two to three minutes following instillation. Observe infants closely for at least 30 minutes.

**HOW SUPPLIED**

2 mL and 5 mL in plastic DROP-TAINER® dispensers.

2 mL NDC 0065-0359-02

5 mL NDC 0065-0359-05

**Storage**

Store at 8° - 27°C (46° - 80°F).

**Rx Only**

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